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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,492	12/03/2001	Lawrence R. Toll	10454-017001	3231

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EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

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DATE MAILED: 08/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,492

Applicant(s)

TOLL ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 41-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-40, in Paper No. 10 is acknowledged.

Claims 41-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 10.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The filing date for provisional application 60/250,743 is incorrect on the oath. The oath lists 12/1/01 whereas the correct date is 12/1/00.

Information Disclosure Statement

Various references have been lined through on the information disclosure statement submitted 4/802 (Paper No. 5). The references provided did not correspond to the cited documents. These references contained no publication information corresponding to that listed and/or the references were clearly drafts or pre-publication documents and not the final published document.

Claim Rejections - 35 USC § 101

Claims 1-40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 is directed to a method comprising specifying a model and comparing a set of sequences to the model. As written, the claimed method recites only data manipulation steps and do not require a concrete, tangible, and useful result. It is noted that the preamble recites "A method comprising" and does not provide the goal or intended result of the method. In addition, it is unclear whether the model recited in the claim is intended to be data (a fixed model, data structure, or statistical description of the sequences) or computer executable code that uses the model and having specific functionality.

Claim 39 is directed to a medium carrying a model. This is considered to be directed to medium containing data which is non-statutory. If applicant intended this claim to be directed to a computer readable medium containing computer executable code with specific functionality, the language used does not set this forth.

Applicant is directed to MPEP 2106 as well as the Trilateral Project WM4 Report on Comparative Study on Protein 3-Dimensional (3-D) Structure Related Claims at:
www.uspto.gov/web/tws/wm4/wm4_3d_report.htm.

Claim Rejections - 35 USC § 112

Claims 1-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

From a careful review of the specification, the invention appears to be comparison of biopolymer sequences expected to be conserved in one region and divergent in the surrounding regions. This comparison is developed into a validated computer model and is used to identify other members related to these sequences. The particular methodology disclosed is an integrated heterogeneous hidden Markov model that models well-preserved and divergent subsequences separately. Particularly of interest are peptide hormones having the structural characteristics set forth in Figures 3 and 4.

As written, none of the claims reflect this invention. None of the claims set forth any steps or methodology in which the scoring of a sequence using a hidden Markov model (or any other model) provides a determination of whether the sequence corresponds to the model. Neither the claims nor specification appear to set forth what the threshold value would be for such a determination. None of the claims set forth any steps or methodology with respect to how the modules of a hidden Markov model (or any other model) are linked or associated with one

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another. The specification does not appear to disclose or suggest any other forms of models other than where the modules are linked. The claims do not require that they be in any way associated. While some of the claims refer to similarity, dissimilarity, and scoring matrices, none of the claims set forth how each score for a sequence from the different modules are used or compared to produce an overall score or determination about the sequence. The specification does not appear to disclose or suggest other forms of scoring.

Claim 1 recites “a first module that characterizes a state of matching between the sequences of the set in a first region” and “a second module that characterizes a state of matching between the sequences of the set in a second region.” Other than in the context of a hidden Markov model with programmed/trained nodes, the specification does not appear to disclose or suggest other types of modules or models containing such modules that are encompassed by the claims. Other than in the context of a hidden Markov model with well understood concepts with respect to “state of matching,” the specification does not appear to disclose or suggest other implementations for this claim limitation. Note that the disclosure on page 10 is not a limiting explanation of what defines a “module.” There is no limiting explanation of what structural or functional (hardware/software) features must be present for the modules and states of matching. The claims as written are not limited to this disclosure.

The claims as written are not enabled because they fail to include critical steps for performing the method such that one of ordinary skill in the art would get a concrete, tangible, and useful result. In addition, it would constitute undue experimentation to develop models other than a hidden Markov model to compare sequences because they specification fails to disclose or suggest other implementations that could be used to practice the claimed method. One of

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ordinary skill in the art would be required to practice experimentation beyond what is routine to develop and validate other models.

Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing in reciting “comparing a given set of sequences” where these sequences are not required to be the same type of biopolymer sequences as in the model.

Claims 3-4 are unclear as to whether the set being referred to is that in the model (“model of a set of biopolymer sequences”) or the set being compared to it (“comparing a given set of sequences to the model”).

Claim 9 is confusing in reciting “scoring matrix that is a function.” It appears that some words have been omitted or that the term “that” should be deleted.

It is unclear whether dependent claim 12 is intending to set forth a positive, active step for the method and if so, what steps must be performed to determine such a probability.

Claim 22 is confusing in reciting “sequence profile.” There is no antecedent basis in claim 1 or 21 for such a profile.

Claim 25 is confusing in referring to multiple sequence profiles. There is no antecedent basis for a plurality of sequence profiles.

Claim 25 is further confusing in reciting a “profile of a processing site.” The metes and bounds of such a profile do not appear to be set forth in the claim. It is not known what information is required to meet this limitation. Claim 23 refers to the sequence profile being

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indicated by altered scoring matrices. It cannot be determined if the altered scoring matrix is the profile intended or it is used to generate the profile. It is unclear how this is accomplished by the method as written.

Claim 26 is confusing in referring to positioning of modules. The modules as set forth in claim 1 do not appear to have position. It seems that perhaps the position of the third region may have been intended with respect to the location of the first and second regions in the sequences.

Claims 27-28 are confusing in reciting "processing site indicates a preference." It is unclear how this is accomplished by the method as written.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-5, 11-18, 21-28, 31, 34, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Nielsen et al. (**Protein Engineering**, 12(1):3-9, 1999).

Applicant is not being given benefit of the filing date of provisional application 60/250,743 as the invention presently claimed is not disclosed in this provisional application. Note that the method as disclosed and claimed in the provisional application differs substantially in the limitations required in comparison with the instant claims.

Nielsen et al. teaches a hidden Markov model for signal peptide and signal anchor prediction wherein which is put together from combined models having different states. Each model included two or three regions. Processing sites were predicted. The processing sites

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included basic residues. Peptide sequences were used to develop the model and a given set of sequences is compared to the model to train and predict. The method is performed on a computer meeting the limitations for claim 39. See abstract, pages 5-7, and Figure 2.


Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa
August 13, 2003